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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,580	07/28/2000	Timothy W. Woudenberg	4291C3	2453

22896 7590 05/31/2002

PATTI SELAN, PATENT ADMINISTRATOR  
APPLIED BIOSYSTEMS  
850 LINCOLN CENTRE DRIVE  
FOSTER CITY, CA 94404

EXAMINER
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SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/31/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/627,580

Applicant(s)

WOUDENBERG ET AL.

Examiner

Khatol S Shahnan-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 2/28/2002 and 3/22/20002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

***Detailed Action***

1. Applicants' amendment B, received March 22, 2002, paper # 7 is acknowledged.

Claim 1 was amended.

2. Terminal disclaimer to obviate a double patenting rejection over prior art, received March 22, 2002, paper # 8 is acknowledged. The disclaimer is proper and has been recorded.

***Objections Withdrawn***

3. Objection to specification in regard to priority statement is withdrawn in view of applicants' amendment B.
4. Objection to specification in regard to typographical errors is withdrawn in view of applicants' amendment B.
5. Objection to specification in regard to compliance with 37 CFR 1.74 (brief description of drawings) is withdrawn in view of applicants' amendment B.

***Rejections Withdrawn***

6. Rejection of claim 1 based on statutory type (35 U.S.C.101) double patenting made in paragraph 8 of the office action mailed 5/2/2001, paper # 5 is withdrawn in view of applicants' amendment B.
7. Rejection of claim 1 based on non statutory type double patenting made in paragraph 9 of the office action mailed 5/2/2001, paper # 5 is withdrawn in view of applicants' terminal disclaimer.

***Rejections Maintained***

8. Rejection of claim 1 under 35 U.S.C. 102 (b) made in paragraph 10 of the office action mailed 5/2/2001, paper # 5 is maintained.

The rejection was as stated below:

Claim 1 rejected under 35 U.S.C. 102(b) as being anticipated by Fadler et al. (US Patent No. 4,038,151).

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Claim 1 is drawn to a device for detecting or quantitating a plurality of different analytes (multiple analytes) in a liquid sample. Comprising a substrate defining a sample –distribution net work of (i) sample inlet, (ii) one or more detection chambers and (iii) channel means providing dead end fluid connection.

Fadler et al. disclose an improved device (card) for detecting or quantitating plurality of different analytes in a liquid sample. (see column 2, lines 27-29). The device comprises a substrate (rigid plastic plate) with a sample distribution network and one or more detection chambers (wells) (see fig 1 column 1). Each of the wells is connected to a predetermined liquid specimen supply port by the means of channels, which provide dead-end fluid connection. The device has means to optically read the viewing wells (see column 2, paragraph 6), can be thermoregulated (see column 4, lines 65-66) and uses vacuum system.

In column 5, lines 34-36 they further teach that: many changes, alterations, modifications and other uses and applications of the subject device will become apparent to those skilled in the art.

Also such a device has been commercially available since the early 1980s from Biomerieux-Vitek Microbiology Systems. See (Baileys and Scott's Diagnostic Microbiology 8th edition, pp.

144-147, fig 11.2) and (attached web site advertisement).

Applicants did not specifically argue this rejection. The rejection is maintained. Applicants amended the claim to recite the new limitation “a plurality of different polynucleotide sequences”. However this is the examiner's position that the claim is drawn to a device and what the device is used for does not impart any criticality on the invention. A polynucleotide sequence is also considered an analyte. Therefore the amended claim 1 is anticipated by the prior art.

Since the office does not have the facilities for examining and comparing applicants' device with the device of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed device and the device of the prior art (i. e., that

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the device of prior art does not possess the same material structure and functional characteristics of the claimed device). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

### *New Grounds for Rejection*

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 1 recites the phrase “ sequence- specific polynucleotide”. It is not clear what applicants intend in recitation of “ sequence- specific polynucleotide”, the phrase is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

### *Conclusion*

10. Claim 1 stands rejected.

11. **THIS ACTION IS MADE FINAL** necessitated by applicants’ amendments. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

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action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30 AM - 4 PM from Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


 5/25/02

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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May 25, 2002

  
LYNETTE B. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600